REMARKS

I. THE CLAIMS ARE NOT INDEFINITE

The Office Action of 13 February 2008 rejected claims 38 and 41 as allegedly indefinite. Applicants have amended the claims to better capture the envisioned commercial embodiments and assert that the claim amendments render moot the indefiniteness rejections. Applicants respectfully request reconsideration and withdrawal of the indefiniteness rejections.

II. THE CLAIMS ARE NOT ANTICIPATED

The Office Action of 13 February 2008 rejected claims 23-25, 27, 38 and 42-44 under 35 U.S.C. §102(b) because Marler *et al* allegedly anticipates these claims. Applicants have amended claim 23 to better capture the envisioned commercial embodiments and assert that the amendments render moot the anticipation rejection. Specifically, Marler does not teach or suggest microparticles of cationic cross-linked alginate, with the alginate being of a high molecular weight. Thus, Marler does not anticipate the present claims. Applicants respectfully request reconsideration and withdrawal of the anticipation rejection.

The Office Action of 13 February 2008 rejected claims 23-25, 29, 31 and 38 under 35 U.S.C. §102(b) because Bent *et al* allegedly anticipates these claims. Applicants have amended claim 23 to better capture the envisioned commercial embodiments and assert that the amendments render moot the anticipation rejection. Specifically, Bent does not teach or suggest microparticles of cationic cross-linked alginate, with the alginate being of a high molecular weight. Thus, Bent does not anticipate the present claims. Applicants respectfully request reconsideration and withdrawal of the anticipation rejection.

The alginate used in the methods of the claimed invention should possess long-term stability and be injectable for increasing tissue volume. The methods require injection of the material. Given that the material is being injected, it is ideal that the material be stable over a period of time in order to ensure that long-term aesthetic effects are achieved. Again, because the alginate is being injected, the material should ideally be highly pure and non-toxic.

Neither Marler nor Bent reflects or teaches the inventive alginate system for tissue augmentation. In fact, Marler and Bent only disclose the commonly used, low molecular-weight alginate. The inventors have discovered that the use of microparticles overcomes problems in the art, since the high molecular weight alginate material, as presently claimed, would not be injectable as such if it were provided as a gel. Indeed, neither Marler nor Bent disclose or even suggest microparticles and they fail to teach or mention high molecular weight alginate material as provided in the presently amended claims because they were both using low molecular weight alginate. Thus, neither Marler not Bent anticipates the present claims. Applicants respectfully request reconsideration and withdrawal of the anticipation rejection.

III. THE CLAIMS ARE NOT OBVIOUS

The Office Action of 13 February 2008 rejected claims 24, 26, 28, 30, and 32-48 under 35 U.S.C. §103 as allegedly being unpatentable over Marler, in view of Bent, Agerup, Vanderhoff, The Merck Index and Hawley's Chemical Dictionary. Applicants respectfully disagree with the Office Action and assert that the claims are not obvious in view of the cited art.

The deficiencies of Marler and Bent have been discussed herein, and neither Vanderhoff nor Agerup cures these deficiencies. Indeed, Vanderhoff relies on covalently crosslinked alginate material and not on material which is ionically crosslinked (see e.g. page 9, last paragraph and page 10, first paragraph of Vanderhoff). The major disadvantage with the Vanderhoff technology is that the covalent crosslinking agents are usually carcinogenic and therefore toxic. In particular, these covalent crosslinkers usually retain their chemical reactivity *in vivo* and thus can be mutagenic. Thus, one of skill in the art would not look to Vanderhoff to prepare compositions to be injected into living subjects. Moreover, the technology disclosed in Vanderhoff cannot possibly be based on ionic linkers, since the molecular weight of the alginate material is much lower than the alginate material presently claimed. In addition, Vanderhoff also requires a complicated emulsion-based production process for allowing the kinetically slow covalent cross-linking to occur, whereas a totally different process provides the microbeads of the present invention. The differences in the production process in Vanderhoff and for the

compositons used in the claimed methods is not trivial, since the production process in Vanderhoff leads to further issues, such as impurities (remainder of the emulsifier) and toxicity.

Agerup also fails to cure the deficiencies of the cited art of record. Agerup is completely different from the subject matter currently claimed, since the document uses to dextranomeric microbeads for tissue augmentation, as the Office Action establishes. Furthermore, Agerup fails to teach the use of high molecular weight alginate, even as a carrier for the dextranomer.

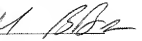
The surprising finding of the invention of the present application is that high molecular weight, ionically-crosslinked alginate material can be used for tissue augmentation. The cited art, individually or collectively, fails to teach or suggest such a composition for use in tissue augmentation methods. This crosslinked alginate material used in the methods of the invention is surprisingly stable over a very long period of time. Moreover, this material does not use any covalent crosslinkers and does not contain any foreign material, which avoids additional toxic effects.

Applicants assert that the references, alone or in combination, do not teach injection of cationic cross-linked alginate (of high molecular weight and in microparticle form) to increase tissue volume. Thus, the references can not be combined to render obvious the presently claimed invention, since the references, alone or in combination, fail to teach each and every element of the currently claimed invention.

CONCLUSION

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,



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